

## Comparison Study Between Various Reported Disintegrating Methods for Fast Dissolving Tablets

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**Abstract:** As disintegration plays an important role in a tablet's dissolution before the active drug substance is finally released from the tablet's structure into the body therefore type, concentration, and efficiency of disintegrates to a large extent affects the disintegrate. Many reports suggest that conventional DT apparatus may not give correct values of DT for ODTs. The time for disintegration of Fast Dissolving Tablets is generally less than one minute. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. In our study we compare various method of disintegration using fast dissolving tablet of Losartan Potassium. The results show that USP Apparatus shows least time i.e. around 20 sec. compared to others for disintegration. The results are as following order: USP < Modified Apparatus II < Modified Apparatus I < Modified Apparatus III.

**Key words:** Losartan Potassium • FDT • Disintegration time • Saliva • Methods

### INTRODUCTION

The oral route of administration is the most important method of administering drugs for systemic effects. Nevertheless it is probable that at least 90% of all drugs used to produce systemic effects are administered by the oral route [1]. Difficulties with and resistance to tablet-taking are common in all patient groups and physical problems with swallowing (dysphagia) can occur at any age but are particularly prevalent in the elderly and those with dementia, whereas refusal to swallow is often encountered in geriatric, paediatric and psychiatric patients [2]. Over the last few years, a great deal of interest has been directed towards formulating solid oral dosage forms that disintegrate/dissolve rapidly in the mouth without the need for water. These dosage forms, known as rapid disintegrating or fast melt tablets [3].

Tablet formulations often include a disintegrating agent, which when it comes into contact with water, disrupts the tablet structure and leads to fragmentation. A larger surface area is thus exposed to the dissolving fluid and dissolution is facilitated. Tablets which contain a large proportion of solids that are freely soluble in water have less need of a disintegrating agent, since such tablets tend to erode from their exterior surfaces rather

than disintegrate. For many years, starch was the disintegrating agent of choice. Recently, however, so-called "super disintegrants" have been introduced, which markedly reduce tablet disintegration time. Such substances include croscarmellose, crospovidone, polacrillin potassium and sodium starch glycolate [4].

One of the most important characteristics of the FDT is its disintegration time in the oral cavity; however, a suitable method to access the disintegration properties described in the Pharmacopoeias (USA, British, Japan and India) has not been developed. At present, the disintegration time of FDT's is measured utilizing the conventional tests (for tablets) that were described in the Pharmacopoeias. However, it is difficult to assess the disintegration rate for the FDT with these tests due to its rapid disintegration rate even in a small amount of water [5].

The time for disintegration of Fast Dissolving Tablets is generally less than one minute. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration time for FDT needs to be modified as disintegration is required without water, thus the test should mimic disintegration in salivary contents [6].

Further, the conventional tests employ a volume of 900 ml of test solution compared to the volume of saliva in humans, which is less than 6 millilitres. Thus, the disintegration rate obtained from the conventional disintegration tests appears not to be reflective of the disintegration rate in the human mouth. To overcome this problem, several new methods have been proposed [7].

**MATERIALS AND METHODS**

Losartan Potassium was obtained as a gift sample from Elfin drug Pvt. Ltd. Nalagarh, H.P (India). Locust bean gum was obtained as gift sample from Lucid Gums, Mumbai, India. AvicelPH-102 was obtained as a gift sample from Helios Pharmaceuticals, Baddi. Aspartame, menthol was purchased from Yarrow Chem. Ambala. Talc and magnesium stearate were purchased from S. D. Fine Chemicals Ltd. Mumbai, India. All other chemicals and reagents used were of analytical grade and used as receive.

**Preparation of Fast Dissolving Tablet:** Fast dissolving tablet tablets containing 25 mg of Losartan Potassium were prepared by direct compression method using formula give in Table 1. The drug and excipients were passed through 60 mesh sieve ensure better mixing. Avicel PH 102 was used as a directly compressible diluent. The directly compressible mixtures were compressed using multi punch tableting machine () fitted with 8 mm flat punches. Before compression, the surface of die and punch were lubricated with magnesium stearate.

**Various Methods Used for Disintegration**

**In vitro USP Disintegration Test:** The test was carried out on 6 tablets using Tablet disintegration tester ED-20 (Electrolab, Mumbai, India) distilled water at 37°C±2°C was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds. One tablet is introduced in to one tube of USP disintegration test apparatus the assembly is suspended in the beaker containing distilled water and the apparatus is operated until the tablet disintegrated and the time required to disintegrate tablet was measured [8-10].

**Modify Disintegrating Test I (Petri Plate Method):** The disintegration time for FDT needs to be modified as disintegration is required without water, thus the test

Table 1: Formula for the preparation of Moth Dissolving tablet

Ingredients	Amt. (mg.)
Losartan Potassium	25
Locust bean gum	15
Avicel-102	122
Aspartame	30
Menthol	2
Magnesium Stearate	4
Talc	2
Total	200



Fig. 1: Disitegtaion Using Petri Plate Mehod



Fig. 2: Disitegtaion Using Basket Method



Fig. 3: Disitegtaion Using Measuring Cylinder Method

should mimic disintegration in salivary contents. For this purpose, a petridish (10 cm diameter) was filled with 10 ml of water (Figure 1). The tablet was carefully put in the centre of Petri dish and the time for the tablet to completely disintegrate into fine particles was noted [6, 11].

**Modifying Disintegrating Test Method II (Basket Method):** This test was carried by placing the FDT in the basket of the USP dissolution basket type apparatus, water was dropped on it from a burette at a rate 4ml per minute (Figure 2). The time taken by the tablet to break in to particles and pass down through the mesh of the basket was noted as disintegrating time. Modifying disintegrating type test II was found to be performed to mimic the less amount of volume of the disintegrating medium present in the mouth [12].

**Modified Disintegration Test Method III (Measuring Cylinder Method):** In this simplest method, 6 mL of phosphate buffer of pH 6.8 was taken in a 25-mL measuring cylinder. Temperature was maintained at 37±2°C. A MDT was put into it and time required for complete disintegration of the tablet was noted [13].

**RESULT AND DISCUSSION**

The amount of saliva available in the oral cavity is very limited (usually less than 6 mL), whereas the conventional DT apparatus uses a large amount of water with very rapid up and down movements. MDT is required to disintegrate in such small amounts of saliva within a minute without chewing the tablet. For this purpose we tried to compare disintegration using various reported method. The result of our study shows that USP disintegration method takes least time i.e. 20 sec. to disintegrate because it employ a volume of 900 ml of test solution compared to the volume of saliva in humans, which is less than 6 millilitre. In the all other method there is no significant difference. The Method II (Basket method) takes less time compared to all among modified test. The reason behind it may be that in this method the drop of disintegration media is falling from a height of 6 cm. which produce force to disintegration.

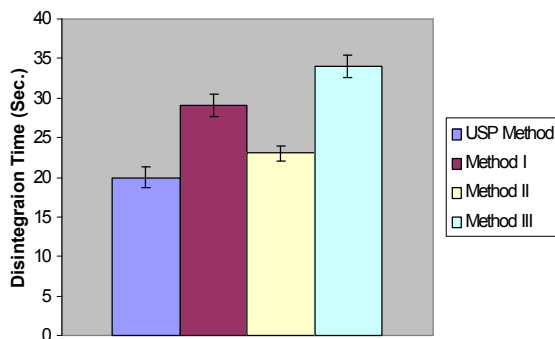


Fig. 4: Comparison data of various disintegration methods

Table 2: Comparison among disintegration methods used in formulation

Method of Disintegration	Time ±SD (Sec.)*
USP disintegrating test	20±1.37
Modifying Disintegrating Test I	29±1.42
Modifying Disintegrating Test II	23±1.04
Modifying Disintegrating Test III	34±1.35

\*n=6

**CONCLUSION**

The time for disintegration of FDTs is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration test for FDT should mimic disintegration in mouth with in salivary content. From our study we have concluded that there is a significant difference between USP dissolution test compare to modified test. The USP method takes least time to disintegrate compared to other. Due to some limitation of USP Test in disintegration of fast dissolving, it should be modified for the fast dissolving.

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